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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of) **MAIL STOP APPEAL BRIEF**
)
KOLTER et al.) Group Art Unit: 1615
)
Serial No. 09/811,546) Examiner: Spear
)
Filed: March 20, 2001)
)

For: SOLID DOSAGE FORMS WITH DELAYED RELEASE OF ACTIVE INGREDIENT AND HIGH MECHANICAL STABILITY

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Honorable Comm'r. of Patents
PO Box 1450
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BRIEF ON APPEAL

Sir:

This appeal is from the examiner's final rejection dated June 18, 2004. Applicants' notice of appeal sent to the USPTO on September 20, 2004.

REAL PARTY IN INTEREST

The real party in interest is BASF Aktiengesellschaft, of Ludwigshafen, Germany. Reel/Frame 011625/0844, recorded on March 20, 2001.

RELATED APPEALS AND INTERFERENCES

To appellants' knowledge and belief, there are no interferences or other appeals which will directly affect or be directly affected by or have a bearing on the Board's

decision in this application.

STATUS OF THE CLAIMS

Claims 1, 3-19 and 21-24 currently are pending in the application.

STATUS OF THE AMENDMENTS

The claims have not been amended subsequent to the final rejection of June 18, 2004.

SUMMARY OF THE INVENTION

The present invention relates to solid oral dosage forms with delayed release of active ingredient and, at the same time, high mechanical stability, comprising besides a preformulated mixture of polyvinyl acetate and polyvinylpyrrolidone and also other water-soluble polymers or lipophilic additives. (Specification, page 1, lines 5-9).

It is an object of the present invention to develop a solid oral dosage form with delayed release of active ingredient and, at the same time, high mechanical stability. (Specification, page 4, lines 40-42). This object is achieved by oral dosage forms with delayed release of active ingredient and high mechanical stability comprising one or more active ingredients, a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone, water-soluble polymers or low or high molecular weight lipophilic additives and other conventional excipients. (Specification, page 4, line 44 to page 5, line 9).

ISSUES

Whether claims 1 , 3-19 and 21-24 are anticipated by Kolter et al. (US

6,064,334) under 35 USC § 102(b).

Whether claims 1, 3-19 and 21-24 are obvious over Kolter et al. in view of Ortega (US 4,837,032).

GROUPING OF CLAIMS

The claims have not been argued separately.

ARGUMENT

The following legal authorities are relied on in the following arguments in the order in which they are cited:

RCA Corp. v. Applied Data Systems, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984)

REJECTIONS

Claims 1, 3-19 and 21-24 are rejected under 35 USC § 102(b) as being anticipated by Kolter et al. The examiner stated that claim 1 of Kolter et al. shows elements a) polyvinyl acetate and b) N-vinylpyrrolidone may constitute the entire binder in a ratio of 6:4 to 9:1 and the upper limit of 20% binder reads on applicants' claim 1.

Applicants' amendment on December 4, 2004 of claim 1 resulted in no overlap of ranges. Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp. v. Applied Data Systems, Inc.,* 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Therefore, Kolter et al. do not teach each and every element of the claims as previously amended.

Claims 1, 3-19 and 21-24 are rejected under 35 USC § 103(a) as being

unpatentable over Kolter et al. in view of Ortega (US 4,837,032). The examiner stated that although Kolter et al. does not recite delayed release of active ingredients within a time of from 0.1 to 1 hour, Ortega is relied on for showing sustained release dosage forms wherein a polymeric matrix is utilized.

Applicants respond by pointing out that it was not expected that varying amounts of PVP/PVAc would lead to tablets with delayed release and a much higher tablet hardness. Applicants also believe that "delayed release" is not a subjective term. Applicants had enclosed a copy from a textbook which clearly shows that delayed release is defined in USP XII and a copy from USP 23 defining immediate release and testing times of upto one hour as appropriate for immediate release. A release occurring over one hour would not be regarded as a delayed release by one of ordinary skill in the art.

Also, applicants' composition is different because the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone combined great mechanical stability with, at the same time, good slowing of release. by the present examples indicate that the present solid dosage form are different and unobvious compared to Ortega et al.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner and the rejection under 35 USC § 103 should be withdrawn.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that reversal of the examiner's rejection of all claims is in order.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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DSK/

APPENDIX

1. An oral dosage form with delayed release of active ingredient and high mechanical stability, comprising

   a) one or more active ingredients

   b) from greater than 20 to less than or equal to 80% a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone

   c) water soluble polymers or low or high molecular weight lipophilic additives

   d) and other conventional excipients,

   wherein the ratio of polyvinyl acetate to polyvinylpyrrolidone is from 6:4 to 9:1.

2. (canceled)

3. An oral dosage form a claimed in claim 1, wherein a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone in the ratio 8:2 is employed.

4. A oral dosage from as claimed in claim 1, which is a tablet, extrudate, pellet or granulate.

5. An oral dosage form as claimed in claim 1, wherein a water-soluble or water-insoluble release-delaying coating is applied to the oral dosage form.

6. An oral dosage form as claimed in claim 1, wherein the water-soluble or lipophilic polymers are selected from the group consisting of: polyvinyl alcohols, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives, and vinyl acetate/vinylpyrrolidone copolymers.

7. An oral dosage form as claimed in claim 1, wherein the water-soluble swelling polymers are selected from the group consisting of: alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives and starch and salts thereof.

8. An oral dosage form as claimed in claim 1, wherein the lipophilic additives are selected from the group consisting of: cellulose derivatives, acrylic ester/methacrylic ester copolymers, fatty alcohols, fatty acids, fatty acid esters and fatty alcohol esters, glycerides, waxes, and lecithin.

9. An oral dosage form as claimed in claim 1, which is produced by direct compression, extrusion, melt extrusion, pelleting, compaction, wet granulation.

10. An oral dosage form as claimed in claim 1, wherein binder, extenders/fillers, disintegrants, lubricants, flow regulators, dyes, stabilizers such as antioxidants, wetting agents, preservatives, release agents, flavorings and sweeteners are employed as conventional excipients.

11. An oral dosage as claimed in claim 1, wherein the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone is present in a proportion of from 10 to 80% based on the total weight of the tablet.

12. An oral dosage form as claimed in claim 1, wherein the water-soluble polymers and/or the lipophilic additives are present in a proportion of from 1 to 40% based on the total weight of the tablet.

13. An oral dosage form as claimed in claim 1, wherein hydroxypropylmethylcellulose

are employed as water-soluble polymers.

14. An oral dosage form as claimed in claim 1, wherein in polyvinylpyrrolidones or vinyl acetate/vinylpyrrolidone copolymers are employed was water-soluble polymers.

15. An oral dosage form as claimed in claim 1, which is a press-coated tablet whose core is rich in active ingredient.

16. An oral dosage form as claimed in claim 1, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.

17. An oral dosage as claimed in claim 1, which comprised active pharmaceutical ingredients as active ingredients.

18. The dosage form as claimed in claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of benzodiazepines, antihypertensives, vitamins, cytostatics, anesthetics, neuroleptics, antidepressants, antibiotics, antimycotics, fungicides, chemotherapeutics, urologicals, platelet aggregation inhibitors, sulfonamides, spasmolytics, hormones, immunoglobulins, sera, thyroid therapeutics, psychopharmaceuticals, antiparkinson agents and other antihyperkinetics, ophthalmologicals, neuropathy products, calcium metabolism regulators, muscle relaxants, lipid-lowering agents, liver therapeutics, coronary agents, cardiac agents, immunotherapeutics, regulatory peptides and their inhibitors, hypnotics, sedatives, gynecologicals, antigout agents, fibrinolytics, enzyme products and transport proteins, enzyme

inhibitors, emetics, perfusion promoters, diuretics, diagnostics, corticoids, cholinergics, biliary therapeutics, antiasthmatics, bronchospasmolytics, beta-receptor blockers, calcium channel blockers, ACE inhibitors, arteriosclerosis remedies, antiinflammatory agents, anticoagulants, antihypotensives, antihypoglycemics, antifibrinolytics, antiepileptics, antiemetics, antidotes, antidiabetics, antiarrhythmics, antianemics, antiallergics, anthelmintics, analgesics, analeptics, aldosterone antagonists, and weight-reducing agents.

19. A drug for delayed release of active ingredients, which is an oral dosage form as claimed in claim 1.

20. (canceled)

21. Food supplements or additives, or vitamins, minerals or trace elements comprising the oral dosage form as claimed in claim 1 for delayed release of active ingredients.

22. An oral dosage form as claimed in claim 6 wherein the water-soluble or lipophilic polymers are selected from the group consisting of polyethylene glycols, polyvinylpyrrolidones, vinyl acetate/vinylpyrrolidone copolymers or maltodextrins, and salts thereof.

23. The oral dosage form as claimed in claim 7, wherein the cellulose derivatives are selected from the group consisting of methylcellulose, methylhydroxyethylcellulose, carboxymethylcellulose and wherein the starch derivatives are selected from the group consisting of carboxymethyl starch,

degraded starch, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers.

24. The oral dosage form as claimed in claim 8, wherein the lipophilic additives are selected from the group consisting of cellulose derivatives which are ethylcellulose, cellulose acetate, cellulose acetate phthalate, cellulose acetate succinate, hydroxy propylmethylcellulose acetate phthalate, or hydroxypropylmethylcellulose acetate succinate, acrylic ester/ethacrylic ester copolymers which are methyl methacrylate/ethyl acrylate copolymers, ammoniomethacrylate copolymer type A and type B, methacrylic acid/acrylic ester copolymers or methacrylic acid/ethyl acrylate copolymers, fatty alcohols which are stearyl alcohols, fatty acids which are stearic acid, fatty acid esters and fatty alcohol esters, glycerides, waxes and lecithin.